Physician-Focused Payment Model Technical Advisory Committee

Preliminary Review Team Findings on:

Oncology Bundled Payment Program Using CNA-Guided Care

Submitted by Hackensack Meridian Health and Cota, Inc.

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Presentation Overview

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Preliminary Review Team (PRT) Composition and Role

- PTAC Chair/Vice Chair assigns two to three PTAC members who have no conflicts of interest (including at least one physician) to serve as the PRT for each complete proposal. One PRT member is tapped to serve as Lead Reviewer.
- PRT identifies additional information needed from the submitter and determines to what extent any additional resources and/or analyses are needed for the review. ASPE staff and contractors support the PRT in obtaining these additional materials.
- After reviewing the proposal, additional information provided by the submitter, information from other materials gathered, and public comments received, the PRT rates the proposal on each of the Secretary's criteria and prepares a report of its findings to the full PTAC. The report is posted to the PTAC website at least two weeks prior to public deliberation by the full Committee.
- The PRT report is not binding on the PTAC; PTAC may reach different conclusions from that contained in the PRT report.

Model Overview (1 of 2)

- Bundled payments for care of patients with newly diagnosed episodes of breast, colon, rectal, and lung cancer.
- 27 bundles; each bundle is an aggregation of “Cota Nodal Addresses” (CNAs) – Cota’s proprietary patient classification system of demographic, biologic, treatment factors
- Each patient assigned a CNA; only patients with a CNA would be enrolled in the model.
- Each CNA has multiple treatment “lanes” – pre-determined sets of treatment protocols developed by the submitter based on their three-year retrospective analysis of patient characteristics, treatments, outcomes, and costs of care.

Model Overview (2 of 2)

- Once a patient receives a CNA, s/he is assigned to a bundle; physician & patient choose the patient's treatment lane from each bundle's treatment lanes.

- Lanes include all processes for patient care including diagnostics, imaging, surgery, chemotherapy, physician visits, follow-up care, comorbidity management and routine care management.

- Through the treatment lane, everything for the patient is prescribed, from the points in time the patient sees the physician, to labs that need to be ordered, to monitoring of patients on chemotherapy.

- Proposal is intended as a pilot for Hackensack Meridian Health (HMH); other entities would implement the model as follow-up to the pilot. Other centers could participate by either purchasing Cota, or those not wishing to utilize Cota could use their own care pathways.

Payment Overview (Provider Payments and Incentives)

- Bundle covers one year starting on day of pathologic diagnosis of cancer
- Prospective bundled payments include cost of oncology care and “unrelated services.”
- HMH will work with CMS using historical claims data on HMH patients to estimate the Medicare 12-month cost (either total or oncology only) for each CNA represented in the patient population.
- The costs of each CNA will be aggregated up to the bundle level using a weighted average approach. These would be used to compute a prospective 12-month price for each of the 27 bundles that cover all the CNAs in the 4 cancer types. HMH would be paid an amount that would be the sum of the bundled price X the number of patients in each bundle.
- Case mix-adjusted payments – if a different mix of patients (as identified through CNAs) presents in the performance year compared to the base year, then the payments will be adjusted to reflect the different mix.

Payment Overview (cont.)

- HMH will receive the prospective payments and use them to compensate providers and pay for care coordination and other uncovered services.

- HMH will be at risk for costs of delivering care if costs exceed what they are paid.

- At the end of a year, the bundle payment will no longer apply to an enrolled patient. All medical services will revert to FFS reimbursement.

- Proposal requests a stop-loss arrangement and proposes a stop-loss threshold at twice bundle payment per patient. “If the expenses for a patient reaches the designated stop loss threshold, such patients will then exit the bundle and be considered outliers.”

- Once a patient is enrolled in a bundle, all claims billed to CMS from any HMH-related provider will be forwarded to HMH. HMH will then pay those claims, and pay physicians based on the standard FFS Medicare rate.

- Part of the compensation to physicians would be incentive-based – based upon services provided, achievement of clinical quality and patient satisfaction outcomes, and total cost of care. HMH does not have plans to place physicians at “downside” risk. Physicians will receive a higher compensation through the bundle if performance metrics are achieved. Physicians who do not meet performance and quality standards will be asked to exit the team and will be unable to participate in any future financial models.

Quality of Care Overview

- Treatment “lanes” based on nationally accepted guidelines; e.g., NCCN, ASCO.
- Compensation to physicians partly based on achievement of clinical quality and patient satisfaction outcomes.
- HMH does not have plans to place physicians at “downside” risk. Physicians will receive a higher compensation through the bundle if performance metrics are achieved. Physicians who do not meet performance and quality standards will be asked to exit the team and will be unable to participate in any future financial models.

Summary of the PRT Review

Criteria Specified by the Secretary (at 42 CFR §414.1465)	PRT Conclusion	Unanimous or Majority Conclusion
1. Scope of Proposed PFPM (High Priority)	Meets criterion	Unanimous
2. Quality and Cost (High Priority)	Meets criterion	Unanimous
3. Payment Methodology (High Priority)	Meets criterion	Unanimous
4. Value over Volume	Meet criterion	Unanimous
5. Flexibility	Meets with priority consideration	Unanimous
6. Ability to be Evaluated	Meets criterion	Unanimous
7. Integration and Care Coordination	Meets criterion	Unanimous
8. Patient Choice	Does not Meet criterion	Unanimous
9. Patient Safety	Meets criterion	Unanimous
10. Health Information Technology	Meets with priority consideration	Unanimous

Criterion 1. Scope of Proposed PFPM (High Priority). The proposal aims to broaden or expand CMS' APM portfolio by either: (1) addressing an issue in payment policy in a new way, or (2) including APM Entities whose opportunities to participate in APMs have been limited.

PRT Conclusion: Proposal Meets the Criterion

- Cancer costs have highest growth rate for any clinical area for several years and predicted to be among the highest cost growth areas for the near future.
- Although proposal addresses a clinical area (and a group of specialist physicians) who already have an alternative payment option with CMS' Oncology Care Model (OCM), numerous aspects of this model are novel and potential improvements over the OCM.
- However, concerns that if the model requires the use of the proposed proprietary software, this could limit its uptake.
- As written, this model not generalizable, although there are some very attractive aspects of this proposal that should be incorporated into an oncology payment model.
- Overall, if viable, the proposed model would be a valuable addition to CMS' portfolio, even though CMS' portfolio already includes the OCM.

Criterion 2. Quality and Cost (High Priority). The proposal is anticipated to (1) improve health care quality at no additional cost, (2) maintain health care quality while decreasing cost, or (3) both improve health care quality and decrease cost.

PRT Conclusion: Proposal Meets the Criterion

- Treatment pathways and monitoring of variance are innovative, evidence-based, and highly likely to reduce unwarranted variation and improve care for patients with cancer.

- Greater precision of diagnosis and treatment compared to OCM (through the use of CNAs and treatment lanes) dramatically reduces chance of inappropriate assignment of patients to bundles:

    1. Patients less likely to be enrolled in a bundle without a documented, auditable need (based on pathology report and captured in the CNA).
    2. Patients unlikely to end up in the wrong bundle given the specificity of the assignment and reliance on prescribed criteria and auditable clinical data.

  Both of these reduce potential for gaming this payment system.

- Some concerns about the implications of having an assigned CNA (and thus all subsequent care decisions defined by that CNA) for the role of patient preferences in ongoing care decisions. Some verification of the pathology and stage, possibly through a clinical audit process, would be reassuring given the significant rate of cancer misdiagnosis reported in the literature.

- Determining the proposal's impact on cost is challenging and depends largely on the bundles pricing. Using costs from a single site to set prices limits pricing to the care patterns at that site. Nonetheless, the prospective nature of the payment method should result in more predictable costs for CMS and should reduce variation in costs for CMS.

- For a pilot, proposal presents a plausible method, but as described, could not be generalized to other sites without further refinement.

Criterion 3. Payment Methodology (High Priority). Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail through this methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

PRT Conclusion: Proposal Meets the Criterion

Potential benefits: Four aspects of model particularly strong and improvements over the existing OCM: 1) Cancer stage included in the grouping; 2) One-year time frame; 3) Case mix adjustment; and 4) Prospective payment.

Concerns:

- Will low frequency of some CNAs affect accuracy of prospective prices?
- Will historical data accurately represent unit costs in the prospective model?
- How will the model handle "leakage" of both patients and doctors?
- How will savings be calculated and will they be valid estimates?
- If it's an "oncology costs only" model (proposal ambiguous on this point), how will oncology costs be isolated?
- Pricing the non-cancer services - costs associated with co-morbid conditions may not reflect the costs in a general population; e.g., PRT analysis found the prevalence of cardiovascular conditions much higher for patients with 3 of the 4 included cancers than in the general population. Thus, proper pricing for non-cancer services would need to adjust for the prevalence of co-morbidities found in each of these cancer populations; and the small number of cancer patients of any particular provider could make provider-level variances very significant.
- The mechanism for initiating the bundle was not well specified in the proposal. The two possibilities, using a pathology claim or a separate communication, need to be examined and tested.
- The model proposes to exclude outliers. Consider winsorization (reducing outlier costs down to some predetermined threshold) a more appropriate approach for dealing with outliers.

Criterion 4. Value over Volume. The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

PRT Conclusion: Proposal Meets the Criterion

Potential benefits:

- Through prospective bundled payments, model provides incentives to practitioners to deliver high quality care.
- Because enrollment is tied to a pathology report, the enrollment criteria make it unlikely that this model could be abused by incentivizing more bundles as can occur with discretionary procedures.
- Protection against skimping on care within bundles addressed by the model's adherence to high quality, evidence-based treatment protocols, with oversight to assure that clinicians are not "free-lancing." (Although this commitment by HMH raises issues of the model's generalizability.)

Concerns:

- Some risk of patients not being enrolled appropriately, and this could be used to create advantageous selection if providers know in advance that a patient will be unusually expensive.
- Submitters rely on the precision of their software and the incentives to reduce costs, however, the proposal does not describe in any detail the mechanism by which costs will be reduced.

Overall: PRT found the risks well balanced.

Criterion 5. Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care

PRT Conclusion: Proposal Meets the Criterion and deserves priority consideration

Flexibility relevant to three different aspects of this proposal: 1) the use of specific software, 2) the use of this type of software (in general), and 3) the impact of the financial model on practitioner behavior.

Concerns:

- If Cota software is required for this model, then the proposed model provides minimal flexibility to practitioners (although this constraint likely to benefit patients by reducing unwarranted variation).
- Lack of transparency of the proprietary software also could overly constrain practitioner behavior and, importantly, affect patients' ability to express their preferences for treatment options.

However:

- The multiple lanes available within each CNA and the explicit linking to NCCN and ASCO guidelines suggest practitioners will have sufficient flexibility to provide optimal care to their patients.
- If any system of cancer care paths can be used with this payment model, and the decision support software ties each and every treatment or service to publicly available evidence, and each recommended action is best standard of care, then the PRT considers this proposal as providing practitioners with adequate flexibility.

Criterion 6. Ability to be Evaluated. Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

PRT Conclusion: Proposal Meets the Criterion

- PRT presumes the evaluation will compare historical to actual costs, possibly using a difference in differences approach.
- Plan to measure patient experience and quality metrics appears appropriate.
- Concerns about the challenges created in the overlap between this proposed model and the Medicare Shared Savings Program.
- The single site, use of proprietary software, and relatively small numbers all limit the ability of this proposal to be evaluated. Or, if one considers the evaluation of a pilot to be more about proof-of-concept than generalizability, then this proposal could be evaluated against that more limited standard.

Criterion 7. Integration and Care Coordination

Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

PRT Conclusion: Proposal Meets the Criterion:

- PRT analysis confirms high rates of co-morbidities (especially cardiovascular conditions) in the target population, so care integration and coordination will be important.

- Payment model encourages care integration and care coordination in a general sense, but there is limited description of the specific nature of the care coordination efforts or of the incentives internal to the organization that would encourage these goals.

- To the extent that care integration is an inherent characteristic of a clinically integrated network, and all providers involved were using the same EHR (both components of the described pilot test of this model), the PRT did not have significant concerns.

Criterion 8. Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

PRT Conclusion: Does Not Meet the Criterion

- Concern that the proposal did not address how patient preferences are to be handled with regard to assignment (or re-assignment) to CNAs, nor is there any description of formal or even informal shared decision-making processes.

- None of the examples of why clinicians might select one or another treatment lane mentioned patient preferences as a reason.

- Given the importance of context-specific choices in cancer care, the PRT found this omission troubling, though the submitters made encouraging statements on this topic during the PRT's interview with them.

Criterion 9. Patient Safety. How well does the proposal aim to maintain or improve standards of patient safety?

PRT Conclusion: The Proposal Meets the Criterion

- The use of HIT to define and monitor the delivery of cancer care should enhance patient safety.

- PRT would like to see attention to the verification of the pathologic diagnosis given research indicating that a significant number of patients are over-diagnosed with cancer and then subsequently subjected to the risks of potentially toxic medications.

Criterion 10. Health Information Technology. Encourage use of health information technology to inform care.

PRT Conclusion: Proposal Meets the Criterion and Deserves Priority Consideration

- The use of HIT to incorporate clinical data into highly specified clinical categories that both define appropriate treatments and monitor variance is a laudable aspect of this proposal.

- In addition, the proposal demonstrates how HIT can be used as a vehicle for improving the payment system by incorporating detailed clinical data into the assignment of patients to specific clinically coherent categories. This grouping supports a payment model that (in concept) appears aligned with clinical care and is less prone to either gaming or errors in performance measurement.

Key Issues Identified by the PRT (1 of 2)

The PRT was impressed by the precision offered by the HMH-Cota model, particularly as compared to CMS' Oncology Care Model already in the field. However, several issues will need to be addressed:

1. **The proprietary nature of the Cota software.** The PRT concluded that the model could be fielded only as a pilot study by Hackensack Meridian Healthcare with possible expansion to other centers in the future. Therefore, by definition the model's reach would be limited to one site initially. Expansion would require either licensing the Cota software or devising a substitute that accomplishes the same precision as the Cota software. Because the payment bundles themselves depend on the specific classification system used in the software, if different software systems were used by different sites then CMS would require multiple payment methods. This seems unrealistic.

Key Issues Identified by the PRT (2 of 2)

2. Related to #1, PTAC should consider whether and how a HMH-Cota pilot study could yield information that would determine if expansion of the model is appropriate. The HMH-Cota pilot's performance measures would be based on comparing its current patients with its historical patients, all of whom will have a Cota Nodal Address designation. CMS would need to determine how this comparison would provide meaningful information about what might be expected if other sites implemented the model, and how their baselines should be calculated.

3. Third, assuming that other hurdles are crossed, should the model be a total cost of care or oncology-costs-only model? Because the proposer appears to be open to either approach, the PRT decided to not assume one or the other but to save the issue for full PTAC discussion.